

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER MDL NO. 19-2875 (RBK)

**CERTIFICATION OF ADAM M. SLATER IN SUPPORT OF  
PLAINTIFFS' *DAUBERT* MOTION TO PRECLUDE  
THE OPINIONS OF DEFENSE EXPERT ALI AFNAN, PH.D.**

**ADAM M. SLATER**, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' motion to exclude the testimony of Defense Expert Ali Afnan, Ph.D.
2. Attached hereto as **Exhibit 1** is a true and accurate copy of the deposition transcript of Ali Afnan in this case.
3. Attached hereto as **Exhibit 2** is a true and accurate copy of ZHP's Investigation Regarding Unknown Impurity (Genotoxic Impurity) of Valsartan API (Version 3) (PRINSTON0076100).
4. Attached hereto as **Exhibit 3** is a true and accurate copy of the FDA's July 23 to August 3, 2018 Establishment Inspection Report (PRINSTON0016249).
5. Attached hereto as **Exhibit 4** is a true and accurate copy of the Stipulation of ZHP in this case.

6. Attached hereto as **Exhibit 5** is a true and accurate copy of ZHP's Investigation Regarding Unknown Impurity (Genotoxic Impurity) of Valsartan API (Version 2) (PRINSTON00075797).

7. Attached hereto as **Exhibit 6** is a true and accurate copy of Plaintiffs' translation of Jinsheng Lin's July 27, 2017 email regarding the NDMA contamination of ZHP's valsartan (ZHP00190573).

8. Attached hereto as **Exhibit 7** is a true and accurate copy of ZHP's translation of Jinsheng Lin's July 27, 2017 email regarding the NDMA contamination of ZHP's valsartan (ZHP00190573).

9. Attached hereto as **Exhibit 8** is a true and accurate copy of ZHP's PowerPoint on the Center of Excellence for Modern Analytical Technologies (CEMAT) (ZHP 432).

10. Attached hereto as **Exhibit 9** is a true and accurate copy of Min Li's CV (ZHP 292).

11. Attached hereto as **Exhibit 10** is a true and accurate copy of the transcript of Min Li's April 20, 2021 deposition in this case.

12. Attached hereto as **Exhibit 11** is a true and accurate copy of the FDA's Warning Letter to ZHP (PRINSTON00077339).

13. Attached hereto as **Exhibit 12** is a true and accurate copy of the transcript of David Chesney's March 21, 2022 deposition in this case.

14. Attached hereto as **Exhibit 13** is a true and accurate copy of the Amended Report of Ali Afnan in this case.

15. Attached hereto as **Exhibit 14** is a true and accurate copy of *Player v. Motiva Enterprises LLC*, No. Civ. 02-3216(RBK), 2006 WL 166452 (D.N.J. Jan. 20, 2006).

16. Attached hereto as **Exhibit 15** is a true and accurate copy of the transcript of Peng Dong's March 29, 2021 deposition in this case.

17. Attached hereto as **Exhibit 16** is a true and accurate copy of an Email Chain Between ZHP and Novartis in June 2018 (ZHP01390017).

18. Attached hereto as **Exhibit 17** is a true and accurate copy of ZHP's Standard Management Procedure for Quality Risk Management (SMP-023) (ZHP00703030).

19. Attached hereto as **Exhibit 18** is a true and accurate copy of the transcript of Peng Dong's March 30, 2021 deposition in this case.

20. Attached hereto as **Exhibit 19** is a true and accurate copy of the transcript of Minli Zhang's March 23, 2021 deposition in this case.

21. Attached hereto as **Exhibit 20** is a true and accurate copy of the transcript of Peng Dong's April 1, 2021 deposition in this case.

22. Attached hereto as **Exhibit 21** is a true and accurate copy of ZHP's ZnCl<sub>2</sub> DMF, Impurities Section (HUAHAI-US00007752).

23. Attached hereto as **Exhibit 22** is a true and accurate copy of ZHP's TEA with Sodium Nitrite Quenching DMF, Impurities Section (PRINSTON00080011).

24. Attached hereto as **Exhibit 23** is a true and accurate copy of Zhejiang Jianye Chemical Co., Ltd.'s Certificate of Analysis for Triethylamine.

25. Attached hereto as **Exhibit 24** is a true and accurate copy of Long & Meek, *Concise International Chemical Assessment Document 31: N,N-Dimethylformamide* (WHO 2001).

26. Attached hereto as **Exhibit 25** is a true and accurate copy of Juillard, *Dimethylformamide: Purification, Tests For Purity And Physical Properties*, Int'l Union of Pure and Applied Chem (Pergamon Press 1977).

27. Attached hereto as **Exhibit 26** is a true and accurate copy of the transcript of Fengtian Xue's February 3, 2023 deposition in this case.

28. Attached hereto as **Exhibit 27** is a true and accurate copy of Sun, Liu, and Zhong, *Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Trimethylamine*, J. Phys. Chem. A. 114, 455-465 (2010).

29. Attached hereto as **Exhibit 28** is a true and accurate copy of *FDA Statement on the FDA's ongoing investigation into valsartan and ARB impurities and the agency's steps to address the root cause of the safety issues* (Jan. 25, 2019).

30. Attached hereto as **Exhibit 29** is a true and accurate copy of the FDA's Important Alert, dated September 28, 2018 (ZHP00061080).

31. Attached hereto as **Exhibit 30** is a true and accurate copy of the FDA's December 5, 2022 Letter to Valisure, LLC.

32. Attached hereto as **Exhibit 31** is a true and accurate copy of an Email Chain Between ZHP and Novartis in May and June 2018 (ZHP00359796).

33. Attached hereto as **Exhibit 32** is a true and accurate copy of USP's General Notices and Requirements, dated April 1, 2015.

**MAZIE SLATER KATZ & FREEMAN, LLC**  
Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: May 13, 2022